

**PHARMACY BOARD[657]****Adopted and Filed**

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 8, “Universal Practice Standards,” Iowa Administrative Code.

The amendment clarifies the requirement for prior notification to the Board when a pharmacy plans to remodel or relocate a pharmacy department, establishing that the notification be submitted to the Board at least 30 days prior to commencement of the project. The amendment also clarifies that the Board may require inspection of the proposed remodel or relocation site, including inspection of a temporary pharmacy location, inspection of a barrier constructed or intended to be constructed to provide security when the pharmacy department is closed, and inspection of a proposed installation of sterile compounding facilities and equipment. The amendment combines two subrules that address requirements for light, ventilation, temperature, and humidity into a single subrule and rennumbers two subrules as a result of the rearrangement and the addition of a new subrule.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the October 3, 2012, Iowa Administrative Bulletin as **ARC 0371C**. The Board received no written comments regarding the proposed amendment. The Board did receive a suggestion from Board staff to specifically require in subrule 8.5(4) prior notification and inspection of new or remodeled sterile compounding facilities and equipment. The adopted amendment differs from that published under Notice by requiring prior notification to the Board and possible inspection of a proposed sterile compounding facility and equipment.

The amendment was approved during the November 9, 2012, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no impact on jobs has been found.

This amendment is intended to implement Iowa Code section 155A.13.

This amendment will become effective on January 16, 2013.

The following amendment is adopted.

Amend rule 657—8.5(155A) as follows:

**657—8.5(155A) Environment and equipment requirements.** There shall be adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy. Space and equipment in an amount and type to provide secure, environmentally controlled storage of drugs shall be available.

**8.5(1) and 8.5(2)** No change.

**8.5(3) Secure barrier:** A pharmacy department shall be closed and secured in the absence of the pharmacist except as provided in rule 657—6.7(124,155A) or 657—7.6(124,155A). ~~The~~ To ensure that secure closure, the pharmacy department shall be surrounded by a physical barrier capable of being securely locked to prevent entry when the department is closed. A secure barrier may be constructed of other than a solid material with a continuous surface if the openings in the material are not large enough to permit removal of items from the pharmacy department by any means. Any material used in the construction of the barrier shall be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent. The plans and specifications of the barrier shall be submitted to the board for approval at least 30 days prior to the start of construction. The board may also require on-site pharmacy may be subject to inspection of the facility or pharmacy department prior to the pharmacy’s opening or relocation as provided in subrule 8.5(4). The pharmacy department shall be closed and secured in the absence of the pharmacist except as provided in rule 657—6.7(124,155A) or 657—7.6(124,155A).

**8.5(4) Remodel or relocation—inspection.** A pharmacy planning to remodel or relocate a licensed pharmacy department on or within the premises currently occupied by the pharmacy department, or a pharmacy intending to remodel or install a sterile compounding facility or equipment, shall provide

written notification to the board at least 30 days prior to commencement of the remodel, pharmacy relocation, or sterile compounding installation. The board may require on-site inspection of the facility, equipment, or pharmacy department prior to or during the pharmacy's remodel, relocation, or opening. The board may also require on-site inspection of a temporary pharmacy location intended to be utilized during the remodel, construction, or relocation of the pharmacy department.

**8.5(4) 8.5(5) *Orderly and clean.*** The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be in good operating condition and maintained in a sanitary manner. Animals shall not be allowed within a licensed pharmacy unless that pharmacy is exclusively providing services for the treatment of animals or unless the animal is a service dog or assistive animal as defined in Iowa Code subsection 216C.11(1).

**8.5(5) 8.5(6) *Light, and ventilation, temperature, and humidity.*** The pharmacy shall be properly lighted and ventilated. The temperature and humidity of the pharmacy shall be maintained within a range compatible with the proper storage of drugs.

~~**8.5(6) *Temperature and humidity.*** The temperature and humidity of the pharmacy shall be maintained within a range compatible with the proper storage of drugs.~~

**8.5(7) and 8.5(8)** No change.

[Filed 11/20/12, effective 1/16/13]

[Published 12/12/12]

EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 12/12/12.